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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/822,698	03/30/2001	Hendricus R.J.M. Hoogenboom	DYX-015.1 US	5332

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EXAMINER

YAEN, CHRISTOPHER H

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 01/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/822,698	Applicant(s) HOOGENBOOM ET AL.	
	Examiner Christopher H Yaen	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 and 70-81 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 3 is/are allowed.
- 6) ☒ Claim(s) 1,2,4-29,70-77 and 79-81 is/are rejected.
- 7) ☒ Claim(s) 78 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The amendment filed 9/29/2003 is acknowledged and entered into the records. Accordingly, claims 30-69 are canceled without prejudice or disclaimer, claims 70-81 are newly added.
2. Claims 1-29 and 70-81 are examined on the merits.

NEW ARGUMENTS

Claim Rejections - 35 USC § 112, 1st paragraph

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-2, 5-14, 74-77, and 79 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection.** Applicant's amendment in claim 1 and dependent claims thereof to include the recitation of "its germline framework or is in a framework from a different polypeptide" is not supported in the specification as originally filed. There is no literal support for using framework regions of the original germ line nor is there support for using "different" framework regions. Applicant is required to remove such limitations from the claim or specifically point to areas in the specification for support of the new claim language.

Claim Rejections Maintained - 35 USC § 112, 1st paragraph

5. The rejection of claims 4-7, 18-29, and newly added claims 70-73, 79, 80 and 81 are maintained for the reasons of record. Applicant argues that the amino acids claimed are rather limited in size and that the homologies claimed would only require a substitution of several (i.e. one or two) amino acid within the claimed sequences. Furthermore, applicant argues that more than one species within a given genus of binding members was presented within the specification. Applicant's arguments have been carefully considered and are not found persuasive. Although there are limited substitutions that could be made within the amino acid sequence claimed, such substitutions have not been clearly taught for all of the claimed sequences. Without the proper identification of all the possible mutations or substitutions claimed, the specification has not provided the skilled artisan with the proper written description of the entire genus claimed. Although the substitutions taught on page 56 may be enough to represent the genus of substitutions for a particular sequence, all the substitutions found on page 56 are represented by a sequence identification number. However, substitutions for all other sequences claimed have not been fully delineated and have not been associated with specific sequences and as such, no representative core structure can be found that is representative of all substitutions made. A reasonable correlation between the structure and function of the substitutions must be provided. There are many epitopes found within the MUC-1 protein and because a nexus between the binding members structure has not been correlated with a particular

Art Unit: 1642

function, one of skill in the art would not be able to determine if the applicant was in possession of all possible binding members claimed.

Claim Rejections Maintained - 35 USC § 112, 1st paragraph

The rejection of claims 15-17 and now newly added claims 74 and 77 under 35 USC 112, 1st paragraph is maintained for the reasons of record. Applicant argues that the germ line sequences were obtain and publically available at the time the invention was made. Applicant's arguments have been carefully considered but are not found persuasive. Reference to Genebank data cannot be relied on for patent purposes because such databases are constantly being updated and as such the skilled artisan may not have access to the exact sequence that is being claimed. Furthermore, the incorporation of essential material in the specification by reference to a foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the applicant, or a practitioner representing the applicant, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. See In re Hawkins, 486 F.2d 569, 179 USPQ 157 (CCPA 1973); In re Hawkins, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); and In re Hawkins, 486 F.2d 577, 179 USPQ 167 (CCPA 1973).

An application as filed must be complete in itself in order to comply with 35 U.S.C. 112; however this does not bar incorporation by reference. Ex parte Schwarze, 151 USPQ 426 (Bd. of Appeals, 1966). An application for a patent when filed may incorporate "essential material" by reference to (1) a United States patent or (2) an

Art Unit: 1642

allowed U.S. application, subject to the conditions set forth below. "Essential material" is defined as that which is necessary to (1) support the claims, or (2) for adequate disclosure of the invention (35 U.S.C. 112). "Essential material" may not be incorporated by reference to (1) patents or applications published by foreign countries or regional patent offices, to (2) non-patent publications, to (3) a U.S. patent or application which itself incorporates "essential material" by reference or to (4) a foreign application. See In re Fouche, 169 USPQ 429; 439 F.2d 1237 (CCPA 1971).

Nonessential subject matter may be incorporated by reference to (1) patents or application published by the United states or foreign countries or regional patent offices, (2) prior filed, commonly owned U.S. applications or (3) non-patent publications, for purposes of indicating the background of the invention or illustrating the state of the art.

Applicant is reminded to provide a Sequence Listing which complies with the requirements of 37 CFR 1.821 through 1.825 for Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Applicant is reminded to provide the appropriate Hawkins Declaration to accompany amending the instant specification to provide the essential subject defining the claimed "germ line" amino acid sequence.

Claim Rejections Maintained - 35 USC § 102

6. The rejection of claims 4-8 and 18-29 under 35 USC 102(b) as being anticipated by Arathoon *et al* is maintained for the reasons of record. Applicant argues that the recited reference does not disclose a MUC-1 binding member and further does not

Art Unit: 1642

specifically teach the specific amino acid sequences claimed. Applicant's arguments have been carefully considered but are not found persuasive because the claims read on sequences that comprise amino acids 55-66 of SEQ ID No: 3. Because the claims are interpreted as open because of the "comprising" language and because the sequence found in Arathoon *et al* is identical to that of amino acids 55-66 of SEQ ID No: 3, the claims are still anticipated by that of Arathoon *et al*, irregardless of the fact that Arathoon *et al* does not specifically teach the exact sequence of 55-66 of SEQ ID No: 3. Furthermore, because the amino acids sequence taught by Arathoon *et al* is identical to that instantly claimed, they too, are at least 70-99% identical.

Claim Rejections Maintained - 35 USC § 102

7. The rejection of claims 4,8 and 18-29 under 35 USC 102(b) as being anticipated by Kanappik A *et al* is maintained for the reasons of record. Applicant's arguments are substantially similar to those made in the above 102(b) rejection (see paragraph 4 of the instant office action). As stated above, the claims are interpreted as being open because of the "comprising" language and as such the sequence that is found in amino acid 31-35 of SEQ ID No: 3 is comprised within a larger sequence. Because the sequences of Kanappik *et al* are identical to those of the instantly claimed invention, they are, in the absence of evidence to the contrary, MUC-1 binding members.

All other rejections are withdrawn in view of the applicant's amendments and arguments thereto as set forth in Paper No. 9292003.

Conclusion

8. Claim 3 appears to be free of the prior art, claim 78 is objected because it depends from a rejected claim.
9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 703-305-3586. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone number for the organization where this application or proceeding is assigned is 703-308-4242.

Application/Control Number: 09/822,698

Page 8

Art Unit: 1642

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Christopher Yaen
Art Unit 1642
December 22, 2003

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DECEMBER 22 2003